Thank you for the Draft Interim Guidance on Financial Relationships in Clinical Research. They are long overdue and generally on target. The only comment I offer on behalf of the patient community are the words "might wish" in section 1.2 and "should consider" in section 5.1 which should be changed to indicate a mandatory rule. These qualifying words leave it up to the discretion of the institution whether they should obtain certain financial information from the investigator, and to decide whether or not research volunteers should be informed of possible conflict of interest by investigators or institutions.

We believe that people who volunteer to participate in research should be informed at a minimum through the informed consent document if the investigator(s) or institution have a possible financial conflict of interest. If the decision about revealing this information is at the discretion of the institution, research participants may never be told. Futhermore, there would be no enforcement mechanism because it is not a mandatory rule. Therefore we strongly suggest that these words should be changed to indicate a mandatory HHS rule. In fact, FDA's current rule requires conflict of interest information to be submitted to the agency AFTER the research is done. The research participant is never told and may not know that their doctor was given recruitment bonuses for entering him/her into the trial. This must be stopped by a MANDATORY rule requiring research volunteers to be told about such arrangements BEFORE they agree to participate in the trial.

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